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DOCUMENTED EVALUATION FOR COMPLIANCE BACKFIT EXCEPTION: DERMAL AND OCULAR CHEMICAL EXPOSURES AT FUEL CYCLE FACILITIES

INTRODUCTION

This document provides the U.S. Nuclear Regulatory Commission (NRC) staff's (staff's) detailed evaluation of a backfit claim presented in a letter dated March 26, 2014, from the Nuclear Energy Institute (NEI) to Marissa Bailey, Director, Office of Nuclear Materials Safety and Safeguards (Agencywide Documents Access Management System [ADAMS] ML14086A267). In an attachment to this letter, NEI presents its position that the staff requires currently-licensed fuel cycle facilities to develop and adopt quantitative exposure standards as part of assessing the consequences of an individual from acute chemical dermal and ocular exposure. NEI's position is that this constitutes backfitting under Title 10 of the *Code of Federal Regulations* (10 CFR) 70.76(a)(1).

The staff's position is that 10 CFR Part 70, Subpart H, promulgated in 2000 (65 FR 56211; September 18, 2000), establishes a set of performance requirements which must be met by the licensee throughout the term of its license. Therefore, changes to the NRC-approved Integrated Safety Analysis (ISA) summary (and underlying ISA) are necessary to ensure continued compliance with the Subpart H performance requirements. As discussed below, following the initial ISA summary approvals, new information showed that dermal and ocular exposures are likely to occur or result in an intermediate or high consequence event. Even if the staff's current position, that fuel cycle facilities ISAs do not meet Subpart H requirements with respect to consideration of dermal and ocular exposure pathways, is considered to be a change constituting backfitting under 10 CFR 70.76, the backfitting would fall within the compliance exception under 10 CFR 70.76(a)(4)(i). This provision excepts the NRC, with an appropriately documented evaluation, from preparing a backfit analysis to support a backfitting action needed for compliance with the NRC's Subpart H requirements. This document constitutes the documented evaluation required by 70.76(a)(4) and Office Instruction NMSS-LIC-253 (ADAMS ML13161A115).

DISCUSSION

A. 10 CFR 70.61, 70.62 and 70.65 are performance-based requirements

The compliance backfit is properly invoked with respect to dermal and ocular exposures, because Subpart H contains performance-based requirements under which the applicant/licensee must address *all credible hazards,* and there is no regulatory language limiting consideration of chemical hazards to specific exposure pathways. Hence, all fuel cycle facility applicants and licensees are under the obligation to address all relevant exposure pathways.

Within 10 CFR part 70 Subpart H, 70.62(c) requires, in relevant part, that a licensee conduct and maintain an ISA that identifies the chemical hazards of licensed material and hazardous chemicals produced from licensed material. 10 CFR 70.61(b) requires that the risk of each credible high-consequence event be limited, and such events include those arising from an

acute chemical exposure as specified in 10 CFR 70.61(b)(4). Similarly, 10 CFR 70.61(c) requires that the risk of each credible intermediate-consequence event be limited, and such events include those arising from an acute chemical exposure as specified in 10 CFR 70.61(c)(4). For all credible event consequences as specified in 10 CFR 70.61(b)(4) and (c)(4), the ISA summary must describe "the proposed quantitative standards used to assess the consequences to an individual from acute chemical exposure to licensed material or chemicals produced from licensed materials," in accordance with 10 CFR 70.65(b)(7).

The regulatory history of the rulemaking adding Subpart H to 10 CFR Part 70 shows that the NRC always intended for 10 CFR Subpart H to be a performance-based regulation. In the drafting of the proposed rule, staff considered various alternative approaches to develop the rule. For example, in SECY-97-097 (ADAMS ML992920141)[1], the staff considered NEI's proposed approach which considered only air pathways criteria and hydrofluoric acid as the only chemical hazard in the rule. However, staff rejected this approach and stated in SECY-97-137 (ADAMS ML003672841) that "all hazards should be identified and considered to determine which hazards could result in accidents which exceed consequence limits" and "chemicals other than hydrogen fluoride will need to be considered." Then, the staff presented a draft proposed rule for Commission consideration[2] including a discussion of air pathway concentration limits (i.e. AEGL and ERPG values) along with a more general discussion of effects (e.g., exposure to hazardous chemicals at concentrations that would cause death or life-threatening injuries). The Commission did not support the proposed rule with regards to chemical safety[3] and directed the staff to consider clarifying the basis for use of chemical safety and chemical consequence criteria in the rule, particularly within the context of the Memorandum of Understanding with the U.S. Occupational Safety and Health Administration (OSHA) and other government agencies.

Accordingly, in 1999, the staff prepared a revised proposed rule[4] including discussions on the clarification of the basis for chemical safety and chemical consequence criteria. Changes to the rule were made to clarify the interface in chemical regulatory authority between NRC and OSHA, changes that were acceptable to NEI and OSHA. Shortly thereafter, the proposed rule was published for public comment (64 FR 41338; July 30, 1999). The statement of considerations (SOC) for the proposed rule stated that Subpart H would establish risk-informed performance requirements (64 FR 41339), and that the ISA would be expected to identify and analyze "all" hazards (64 FR 41346). The 1999 SOC also stated that the requirements for chemical hazards and accident analysis, that NRC was then proposing to add, were intended to "complement and be consistent with the parallel OSHA and EPA regulations" (64 FR 41340).

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[1] SECY-97-097 (May 2, 1997), "Additional Alternative for Regulating the Safety of Fuel Cycle Facilities: Nuclear Energy Institute Petition for Rulemaking", ADAMS ML992920141

[2] SECY-98-185 (July 30, 1998), "Proposed Rulemaking- Revised Requirements for the Domestic Licensing of Special Nuclear Material". Appendices to the draft proposed rule presented AEGL and ERPG values. ADAMS ML992910107

[3] SRM-98-185, (December 1, 1998), "Proposed Rulemaking- Revised Requirements for the Domestic Licensing of Special Nuclear Material". ADAMS ML003755356

[4] SECY-99-147 (June 2, 1999), "Proposed Rulemaking- Domestic Licensing of Special Nuclear Material". ADAMS ML992850039

This language supports the staff position that the NRC has interpreted Subpart H as requiring consideration of *all* relevant and credible exposure pathways, which is consistent with OSHA regulations that also require consideration of all exposure pathways. In discussing proposed standards used to assess consequences of hazards (64 FR 41342-43), the 1999 SOC focused on air pathway limits because at the time of the rulemaking, the air pathway standards were the ones that were readily available for a broad suite of chemicals. National efforts were then underway to improve the emergency response following major chemical release accidents, and were therefore available for adoption in ISAs.

In sum, the NRC's interpretation of the requirements of Subpart H has not changed, and the regulatory wording has not changed. The NRC adopted subpart H as a set of performance-based requirements which are not limited to specific exposure pathways. Instead, the NRC's regulatory approach embodied in subpart H requires the applicant/licensee to identify and justify in the ISA summary the relevant and credible exposure pathways.

B. Compliance of ISA summaries with the performance requirements of 10 CFR 70.61

At the time of NRC approval of the original ISA summaries, the air pathway was: (i) the only exposure pathway that was considered by industry and reviewed by NRC to have the potential for offsite consequences, and (ii) the more dominant (but not exclusive) pathway for worker exposure following an accident. Accordingly, during the 2005-2007 timeframe, ISA summaries were approved without explicitly documenting a finding on dermal and/or ocular exposure. Approval of the initial ISA summaries without consideration of dermal or ocular exposures was consistent with the performance-based requirements of 10 CFR 70.61.

Shortly after the initial ISAs were approved, the NRC issued Information Notice (IN) 2007-22, "Recent Hydrogen Fluoride Exposures at Fuel Cycle Facilities" (ADAMS ML071410230). The IN explained that hydrogen fluoride (HF) presents a hazard in different stages of the nuclear fuel cycle. During conversion, HF is used in the production of uranium hexafluoride (UF6). During fuel fabrication, UF6 is sublimed and hydrolyzed. The IN reported two exposure events that had occurred in fuel cycle facilities regarding acute chemical exposures including dermal exposures (ADAMS ML072620314 and ML070650158). The IN stated that licensees should consider all routes of exposures that could lead to intermediate and high consequence. Since IN 2007-22, there have been other events reported to the NRC in which fuel cycle facility workers experienced dermal and ocular exposures to HF and other hazardous chemicals[5]. These events demonstrate the continued potential for dermal or ocular exposures and therefore, the need to consider them in the ISA. Hence, ISAs that do not consider dermal and ocular exposure events at NRC-licensed fuel cycle facilities -- are no longer acceptable[6]. Therefore, the NRC position that dermal and ocular exposure pathways must be considered in ISAs when

[5] Event Notification (EN) 46749 (ML111330552), EN46799 (ML11144A184) and EN49437 (ML13316A254).

[6] Licensees modified their ISA summaries to include consideration of dermal and ocular exposure for HF and propose a quantitative standard for HF. These actions support the NRC's position that dermal and ocular exposure pathways are credible, and therefore must be analyzed in accordance with 10 CFR 70.65.

analyzing acute chemical exposures, in order to meet the subpart H performance requirements, represents compliance backfitting[7].

In sum, the original NRC approval of ISA summaries which do not explicitly address dermal and ocular exposure pathways was based on the NRC understanding (shared by the industry) that dermal and ocular exposures were not likely to result in an intermediate or high consequence. Subsequent information showed that the NRC and licensee understanding in this regard was incorrect. Thus, any backfitting with respect to dermal and ocular exposures is needed for compliance with the NRC staff's unchanged interpretation of the requirements of Subpart H.

CONCLUSION

Existing fuel cycle facilities, regulated under Subpart H, must consider all relevant and credible pathways when analyzing for acute chemical exposure in the ISAs, including dermal and ocular exposure pathways. Existing NRC-approved ISA summaries, which do not consider such pathways, are not in compliance with the performance requirements of Subpart H. Licensees whose ISA summaries do not explicitly address dermal and ocular exposure pathways must modify their existing ISAs to include such consideration of dermal and ocular exposures, and must describe in their ISA summaries the quantitative standards for such exposures, in accordance with 10 CFR 70.65(b)(7). This position will also be applied to future fuel cycle facility applications. This would not constitute backfitting, as future applicants are not protected by 10 CFR 70.76 with respect to backfitting.

[7] NRC letters to NEI, dated November 10, 2008, June 12, 2009, and August 16, 2010 (ML082900889, ML090920296, and ML093440038),